MAR - 8 2001

510(k) SUMMARY

K 003787

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

IDENTIFICATION OF SUBMITTER

ZeroBase-USA LLC

Prepared on October 24, 2000 by:
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IDENTIFICATION OF PRODUCT

Name	NewTom Model QR-DVT 9000
Manufacturer	NIM s.r.l. Via Silvestrini, 20 37135 Verona Italy
Distributor	ZeroBase-USA LLC 315 Laurens Street Olean, NY 14760

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MARKETED DEVICES

The NewTom model QR-DVT 9000 is substantially equivalent to the devices listed below:

Predicate Device 1 (*"PD1"*) (for the NewTom software)

Device	Advantage 3-D XR
Manufacturer	General Electric Medical Systems 283, rue de la Miniere 78533 Buc Cedex FRANCE
510(k) #	K974715

Predicate Device 2 (*"PD2"*) (for the NewTom gantry and patient table)

Device	Advantx LCA
Manufacturer	General Electric Medical Systems 283, rue de la Miniere 78533 Buc Cedex FRANCE
510(k) #	K945375

DEVICE DESCRIPTION

The NewTom QR-DVT 9000 is a dedicated X-Ray imaging device that uses an X-Ray imaging system and a patient table. The NewTom acquires a 360° rotational X-Ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two-dimensional views of this volume, displaying both two-and three-dimensional images. The NewTom can measure distances and thickness on two-dimensional images.

Images produced by the NewTom can be printed or exported on magnetic and optical media.

The NewTom is designed for use in diagnostic support both in odontoiatric radiology, with a particular reference to the "planning" and to monitoring of implantations, and in the field of maxillofacial surgery.

The NewTom hardware, including a patient table and gantry (comprised of an X-Ray source, image chain and a motorized arm) facilitates the acquisition of a full X-Ray sequence by the device's software. The NewTom software runs either on a Windows NT 4.0 workstation or on a Windows 9x workstation (on a Windows 9x workstation the scan is disabled and can be used only for data analysis).

INTENDED USE

The NewTom QR-DVT 9000 is an X-Ray imaging device that constructs a three-dimensional model from images taken during a rotational X-Ray sequence. The NewTom is optimized for bone morphology analysis on the maxillofacial region.

COMPARISON WITH THE PREDICATE DEVICE

The NewTom QR-DVT 9000 reconstructs a three-dimensional model from X-Ray images similar to the three-dimensional model obtained using the Advantage 3-D XR option and the Advantx LCA angiography system. It displays either two-dimensional cross-sections or three-dimensional views and allows the user to take measurements (distances and angles) on the reconstructed volume.

CONCLUSION

The NewTom QR-DVT 9000 acquires an X-Ray rotational sequence and provides three-dimensional information on the analyzed volume. The potential hazards (*e.g.*, electrical, mechanical, thermal, radiation, incorrect measurement, and misdiagnosis) are controlled by the NewTom's risk management system including:

- A hazard analysis performed according to a fault tree which indicates an extremely low probability of harmful events;
- A hardware and software development and validation process under the EN 46001 quality system; and
- Adherence to International Standards - International Electrotechnical Commission (IEC).

The NewTom QR-DVT 9000 is an X-Ray imaging system that complies with the requirements of 21 C.F.R. Part 807.87(h), and does not pose any new safety risks or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

ZeroBase-USA LLC
c/o Gregory W. Bowman, Attorney
Baker & McKenzie
Attorneys At Law
815 Connecticut Avenue, N.W.
WASHINGTON DC 20006-4078

Re: K003787
NewTom Model QR-DVT 9000
Dated: December 8, 2000
Received: December 8, 2000
Regulatory Class: II
21 CFR §892.1650/Procode: 90 JAA
21 CFR §872.1800/Procode: 90 MUH

Dear Mr. Bowman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

David A. Segerson

David A. Segerson
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

Version:
00

Applicant:

ZeroBase-USA, LLC

510(k) Number (if known): K003787

Not known

Device Name:

NewTom QR-DVT 9000

Indications For Use:

The NewTom QR-DVT 9000 is a dedicated X-Ray imaging device that acquires a 360° rotational X-Ray sequence for use in diagnostic support in odontoiatric radiology (with a particular reference to patient evaluation and the monitoring of implantations) and in the field of maxillofacial surgery.

The NewTom QR-DVT 9000 accomplishes this task by reconstructing a three-dimensional matrix of the examined volume and producing two-dimensional views of this volume, displaying both two-and three-dimensional images.

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jegorow

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003787

Prescription Use ✓